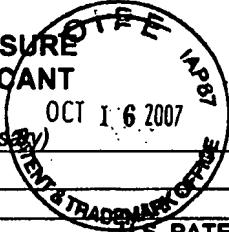


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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | |  OCT 16 2007 | | Complete if Known | |
| | | Application Number | 09/525,797 | | |
| | | Filing Date | March 15, 2000 | | |
| | | First Named Inventor | Athanasius A. Anagnostou | | |
| | | Group Art Unit | 1642 | | |
| | | Examiner Name | Susan Ungar | | |
| Sheet 1 | of 2 | Attorney Docket Number | 5218-39B | | |

| U.S. PATENTS AND PATENT PUBLICATIONS | | | | | |
|---|----------|----------------------|-------------------------|---|---|
| Examiner Initials* | Cite No. | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY |
| | | Number | Kind Code (if known) | | |
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| U.S. PATENT APPLICATIONS | | | | |
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| Examiner Initials* | Cite No. | U.S. Serial No. | Name of Applicant of Cited Document | Date of Filing of Cited Document MM-DD-YYYY |
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| FOREIGN PATENT DOCUMENTS | | | | | |
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| Examiner Initials* | Cite No. | Foreign Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY |
| | | Office | Number | | |
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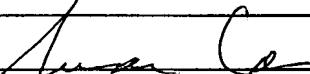
| OTHER NON PATENT LITERATURE DOCUMENTS | | | | | |
|--|----------|--|--|--|--|
| Examiner Initials* | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | | | |
| | 1. | English translation of "Notice of Opposition" filed by Bioceuticals Arzneimittel AG 1-6 (2005) including the following D1-D9 annexed documents | | | |
| SU | D1 | WO 98/10650 to East Carolina University 03/19/1998 including International Search Report dated 10/24/1997 | | | |
| | D2 | Rubins et al. "Metastatic Renal Cell Carcinoma" <i>Annals of Internal Medicine</i> 122(9):676-677 (1995) | | | |
| | D3 | Carlini et al. "Recombinant human erythropoietin stimulates angiogenesis <i>in vitro</i> . <i>Kidney International</i> 47:740-745 (1995) | | | |
| | D4 | Höckel et al. "Therapeutic Angiogenesis" <i>Arch Surg</i> 128:423-429 (1993) | | | |
| | D5 | Sungur, Cem "Renal Cell Carcinoma and Erythropoietin" <i>Annals of Internal Medicine</i> 123(9):732-733 (1995) | | | |
| | D6 | Anagnostou et al. "Erythropoietin has a mitogenic and positive chemotactic effect on endothelial cells" <i>Proc. Natl. Acad. Sci.</i> 87:5978-5982 (1990) | | | |
| | D7 | Carlini et al. "Recombinant human erythropoietin (rHuEPO) increases endothelin-1 release by endothelial cells" <i>Kidney International</i> 43:1010-1014 (1993) | | | |
| | D8 | Nagai et al. "Effects of rHuEpo on cellular proliferation and endothelin-1 production in cultured endothelial cells" <i>Nephrol Dial Transplant</i> 10:1814-1819 (1995) | | | |
| | D9 | Yamaji et al. "Brain capillary endothelial cells express two forms of erythropoietin receptor mRNA" <i>Eur. J. Biochem</i> 239:494-500 (1996) | | | |
| | D10 | Miller et al. "Phase I-II Trial of Erythropoietin in the Treatment of Cisplatin-Associated Anemia" <i>J Natl Cancer Inst</i> 84(2): 98-103 (1992) | | | |
| | 2. | English translation of "Observations of Patentee in Reply" 22 pages (2006) including the following A1-A8 annexed documents | | | |
| | A1 | English translation of the Opposition Statement | | | |
| | A2 | Timeline of treatments given to patient of D1 (1 page) | | | |
| | A3 | Prescribing information for Procrit® (1-36) (2005) | | | |
| | A4 | BCCA Protocol Summary for Alpha-interferon (α-IFN) for Advanced Renal Cell Carcinoma (2006) | | | |
| | A5 | Neidhart, J.A. "Interferon therapy for treatment of renal cancer" <i>Cancer</i> 57(8 Suppl):1696-1699 (1986) | | | |
| | | ABSTRACT | | | |

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|--------------------|--------------------|-----------------|----------|
| Examiner Signature | <i>Susan Ungar</i> | Date Considered | 11/21/07 |
|--------------------|--------------------|-----------------|----------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| | | First Named Inventor | Athanasius A. Anagnostou |
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| Sheet 2 | of 2 | Attorney Docket Number | 5218-39B |

| OTHER NON PATENT LITERATURE DOCUMENTS | | |
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| Examiner Initials* | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published |
| SU | A6 | Whiteway et al. "An extremely delayed cytogenetic response to interferonalpha in a patient with chronic myeloidleukaemia" <i>Leukemia</i> 11(4):614-616 (1997) <i>Abstract only</i> |
| | A7 | < http://www.cancerguide.org/rcc_metastatic.html > 1-4 (2006) |
| | A8 | < http://www.noetic.org/research/sr/faqs/html > 1-4 (2006) |
| | 3. | English translation of "Response to the Patentee's Observations of 27 th April 2006" 1-17 (2006) including the following D11-D13 annexed documents |
| SU | D11 | Shinkelgaku et al. "Multiple cerebral infarction after treatment with cisplatin" <i>Rinsho Shinkeigaku</i> 36(3):499-502 (1996) ABSTRACT |
| | D12 | Ito et al. "Vitamin E prevents endothelial injury associated with cisplatin injection into the superior mesenteric artery of rats" <i>Heart Vessels</i> 10(4):178-184 (1995) ABSTRACT |
| | D13 | Breymann et al. "Optimal timing of repeated rh-erythropoietin administration improves its effectiveness in stimulating erythropoiesis in healthy volunteers" <i>Br J Haematol</i> 92(2):295-301 (1996) ABSTRACT |
| | 4. | English translation of "Opponent's Rule 71A EPC Submissions File" 1-40 2007 |
| | 5. | English translation of "Patentee's Rule 71(a) EPC Submissions 29 pages (2007) including the following A9-A13 annexed documents |
| | A9 | English translation of the Opposition statement 1-17 |
| | A10 | Expert Witness Statement of Professor Alexander F. Markham including his Curriculum Vitae 1-51 (2006) |
| SU | A11 | Freed et al. "Idiopathic Regression of Metastases from Renal Cell Carcinoma" <i>The Journal of Urology</i> 118:538-542 (1977) |
| | A12 | <i>In vivo</i> further experimental data from the Patentee (cisplatin and tumour weight and volume) |
| | A13 | <i>In vivo</i> further experimental data from the Patentee (bleomycin and functional changes of the epithelium) (2 pages) |

| | | |
|--------------------|---|-----------------|
| Examiner Signature |  | Date Considered |
|--------------------|---|-----------------|

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